

1 HERNIA PROSTHESIS

2

3 **FIELD OF THE INVENTION**

4

5 The present invention relates to prostheses for
6 repairing or resisting the formation of bodily
7 hernia in particular, but not exclusively, for
8 inguinal hernia repair or femoral hernia repair and
9 a method of using said prostheses.

10

11 **DISCUSSION OF THE PRIOR ART**

12

13 A hernia is due to an abnormal protrusion of an
14 organ or part thereof through its containing
15 structure, due to a rupture or weakening in a layer
16 of fascia creating an aperture or a defect in the
17 fascia which causes it to be less able to contain
18 the organ or part thereof. Hernia can occur at
19 various anatomical positions in the abdomen where
20 there is a weakness in the muscle, and are
21 classified according to the site in which they
22 occur.

1

2 Two particular types of hernia are inguinal hernia
3 and femoral hernia.

4

5 Inguinal hernia occur in the groin when a portion of
6 bladder, bowel or membrane pushes through a weak
7 spot in the abdominal musculature around or at the
8 inguinal canal. The inguinal canal is an opening
9 between layers of abdominal muscle near the groin
10 through which the spermatic cord passes in the male.
11 Typically, inguinal hernia is a male condition.

12

13 Two particular types of inguinal hernia occur,
14 direct inguinal hernia and indirect inguinal hernia.

15

16 An indirect inguinal hernia passes through the
17 internal ring of the inguinal canal, along the canal
18 and, if the hernia is large enough, emerges through
19 the external ring and in the male descends into the
20 scrotum.

21

22 A direct inguinal hernia differs from an indirect
23 inguinal hernia as it pushes its way directly
24 forwards through the posterior wall of the inguinal
25 canal. Occasionally, in unusual circumstances, a
26 direct hernia becomes large enough to push its way
27 through the external ring and then into the neck of
28 the scrotum.

29

30 The femoral artery and vein enter the femoral
31 triangle from beneath the inguinal ligament within a
32 fascial tube termed the femoral sheath. The femoral

1 canal is a small, almost vertically-placed gap in
2 the medial part of the femoral sheath. The function
3 of the femoral canal is to firstly act as a dead
4 space for expansion of the distended femoral vein
5 and secondly as a lymphatic pathway from the lower
6 limb to the external iliac nodes.

7
8 The femoral canal is a potential point of weakness
9 in the abdominal wall which may develop a femoral
10 hernia. The canal is around 1 to 1.5 cm in length.
11 As the female pelvis is of greater width than the
12 male pelvis, the femoral canal can be somewhat
13 larger in females and female femoral hernia are more
14 common. A femoral hernia is a protrusion through the
15 femoral canal. The hernia sac may extend through
16 the femoral canal.

17
18 Hernia repair generally requires the contents of the
19 hernia to be eased back into position and then for
20 the weakened area to be repaired. Repair can be
21 effected by tension or tension-free suturing of the
22 tissue and muscle to strengthen the weakened area or
23 occlude ruptured areas. Alternatively, the weakened
24 or ruptured area can be reinforced using a portion
25 of synthetic mesh.

26
27 Meshes for use in the treatment of an inguinal or
28 femoral hernia typically consist of a flat portion
29 of mesh for application over the hernia area. The
30 mesh allows a tension free repair to be made of the
31 weakened area. Such flat meshes have been provided
32 with an aperture therein or may be cut by a surgeon

1 to allow the mesh to be arranged around an
2 anatomical structure which passes through the
3 opening or defect in the tissue, muscle or organ
4 wall requiring repair or support.

5

6 Alternatively, for a well circumscribed defect, e.g.
7 a deep inguinal hernia or femoral hernia, the repair
8 device may be an implantable prosthesis which stops
9 the rupture hole of the hernia.

10

11 Implantable prostheses of the prior art include the
12 Bard PERFIX plug TM, Ethicon's Prolene Hernia System
13 TM, and Surgipro Hernia Mate plug and Patch TM or
14 Atrium Self-forming plugs TM.

15

16 The Bard PERFIX plug TM is one of the most popular
17 plugs and comprises a surgical mesh fabric arranged
18 to form around 8 leaves or petals, which are joined
19 in a central region to create a multi-layered cone.
20 The central portion of the plug is pushed into the
21 defect and the leaves trimmed according to the size
22 of the defect such that they stop the defect. As
23 the leaves project from the central portion, these
24 aid the retention of the plug in the defect. In
25 addition, an overlay patch may be positioned over
26 the plug which surrounds those tissues surrounding
27 the inguinal canal. Surgipro Hernia Mate plug and
28 Patch TM and Atrium Self-forming plugs TM also
29 comprise several leaves and an overlay patch and
30 work in a similar fashion to the Bard product.

31

1 Ethicon's Prolene Hernia System TM comprises a first
2 overlay patch for placing around the inner ring of
3 the inguinal canal, a central portion and a second
4 overlay patch for placing around the outer ring of
5 the inguinal canal. The central portion corresponds
6 to both a portion of the first and second overlay
7 patches such that it is held in the inguinal canal
8 by the two patches to block the canal.

9
10 In use, the implantable prostheses of the prior art
11 block the inguinal canal and prevent a hernia sac
12 from protruding through the canal. The defects
13 blocked most effectively by the prostheses are
14 substantially circular in cross section, as multi-
15 layer prostheses are inherently stiff and may not
16 fully conform to variations in the defect. In some
17 circumstances, when a prosthesis is in use, gaps may
18 be potentially left between the prosthesis and the
19 surrounding tissue, muscle or organ wall of the
20 opening or defect.

21
22 This potential for gaps can be increased by
23 anatomical structures which under normal
24 circumstances pass through the inguinal canal, such
25 as the spermatic cord, and protrude at the edge of
26 the prosthesis and this causes difficulty in
27 completely occluding the defect.

28
29 To improve the flexibility of conventional
30 prostheses and thus minimise the potential gaps
31 between the prostheses and surrounding tissues, some
32 prostheses include pleats moulded into the body of

1 the prostheses. Although, such pleats may to some
2 extent accommodate anatomical structures which pass
3 through the defect in the tissue, as such a
4 prosthesis relies on a push fit of the prosthesis
5 into the defect and radial expansion of the leaves
6 of the prosthesis against the tissues surrounding
7 the defect to hold the implant in place, such a
8 prosthesis will compress anatomical structures
9 between the prosthesis and the surrounding tissue.
10 This compression can result in a significant
11 pressure being experienced by an anatomical
12 structure.

13

14 Significant pressure is a pressure which causes
15 distortion, compression or full or partial collapse
16 of an anatomical structure. For example, in
17 particular examples where a conventional prosthesis
18 is used to treat inguinal hernia, the spermatic cord
19 is squeezed between the prosthesis and the tissues
20 surrounding the aperture and this squeezing may
21 cause pain or even damage to the spermatic cord.
22 This can lead to discomfort for the patient and
23 might lead to long term damage to the structure(s)
24 being compressed and may cause ischaemia of a distal
25 organ. For example, where the anatomical structure
26 includes the spermatic cord, ischaemia of the testes
27 may occur as a result of compression of the artery
28 and/or vein along with the spermatic cord.

29

30 According to the present invention there is provided
31 a prosthesis for repair or to resist the formation
32 of hernia of the abdominal wall, the prosthesis

1 comprising at least an outer surface and an inner
2 surface wherein, the inner surface forms at least
3 one channel through which, in use, an anatomical
4 structure may pass when the prosthesis is in place
5 in the body without substantial compression of said
6 anatomical structure.

7

8 The channel may be an indentation in the outer
9 surface of the prosthesis.

10

11 Preferably the channel is formed along the outer
12 surface of the prosthesis.

13

14 An advantage of a prosthesis of the present
15 invention is that by providing such a channel in the
16 prosthesis, pressure on an anatomical structure
17 passing through the channel can be minimised. A
18 reduction or complete removal of the pressure on an
19 anatomical structure should minimise damage and / or
20 discomfort caused by compression of anatomical
21 structures passing through the defect being repaired
22 and minimise the rupture or protrusion of a hernia
23 sac through the defect.

24

25 In a preferred embodiment of the prosthesis the
26 inner surface defines a scalloped channel.

27

28 A scalloped channel is formed by the intersection or
29 indentation of a cylinder with the outer surface of
30 the prosthesis.

31

32 In a particularly preferred embodiment of the

1 prosthesis the channel has a substantially semi-
2 circular edge in cross section, such that the inner
3 surface is substantially curved as it interfaces
4 with the anatomical structure which the channel
5 receives.

6

7 Preferably, in use, the prosthesis is always wholly
8 contained within the extra peritoneal compartment of
9 the abdominal wall.

10

11 Preferably the prosthesis is suitable for use in the
12 treatment of abdominal hernia. More preferably the
13 prosthesis is suitable for treatment of inguinal or
14 femoral hernia.

15

16 In an embodiment of the prosthesis, the prosthesis
17 is provided for repairing or resisting the formation
18 of an inguinal hernia, the channel being sized to
19 accommodate a spermatic cord without substantial
20 compression of the spermatic cord.

21

22 In a preferred embodiment of the prosthesis, wherein
23 the prosthesis is for use in repairing or resisting
24 the formation of an inguinal hernia, the prosthesis
25 has a longitudinal length or depth in the range 1 cm
26 to 5 cm. More preferably the prosthesis has a
27 longitudinal length in the range of between 2 cm to
28 3 cm.

29

30 In a preferred embodiment of the prosthesis for use
31 in repairing or resisting the formation of an
32 inguinal hernia, the prosthesis is of width or

1 diameter in the range 0.5 cm to 7 cm. In a
2 particular embodiment the prosthesis is of width or
3 diameter in the range 1 cm to 4 cm.

4

5 In a particularly preferred embodiment of the
6 prosthesis for repairing or resisting the formation
7 of an inguinal hernia, the prosthesis has a
8 truncated conical shape wherein the outer surface of
9 the prosthesis is formed by the conic surface.

10

11 A prosthesis of truncated conical shape in which a
12 first end of the prosthesis has a diameter less than
13 that of a second end has the advantage that the
14 prosthesis can be pushed first end into the defect,
15 to plug the defect more easily.

16

17 In a particularly preferred embodiment, the
18 prosthesis is of truncated conical shape and further
19 comprises a semi-circular channel extending from a
20 first end of the prosthesis to a second end of the
21 prosthesis, the first end having a diameter less
22 than the second end, wherein the semi-circular
23 channel is present in the conic outer surface of the
24 prosthesis such that in cross-section a crescentic
25 shaped prosthesis is provided.

26

27 In an embodiment wherein the prosthesis has a
28 truncated conical shape, the diameter of the widest
29 end of the prosthesis, the second end, is preferably
30 in the range 1 cm to 7 cm and the diameter of the
31 narrowest end, the first end, is preferably in the
32 range 0.5 cm to 4 cm.

1
2 The channel receiving the anatomical structure can
3 have any suitable cross sectional shape such as a
4 semi-circular cross section. In an embodiment of
5 the prosthesis for repairing or resisting the
6 formation of an inguinal hernia, the channel is
7 sized in the range 0.5 cm to 3 cm in width and depth
8 or where the channel of such an embodiment of the
9 prosthesis is of circular or substantially circular
10 cross section, for example semi-circular cross
11 section, the channel is in the range 0.5 cm to 3 cm
12 in diameter.

13
14 In another embodiment of the prosthesis, the
15 prosthesis is provided for repairing or resisting
16 the formation of a femoral hernia. In such an
17 embodiment the length of the prosthesis is in the
18 range 1 cm to 5 cm, the width of the prosthesis is
19 in the range 0.5 cm to 7 cm and the channel is sized
20 to receive at least one of a femoral vein or other
21 anatomical structure.

22
23 In a preferred embodiment of a prosthesis provided
24 for repairing or resisting the formation of a
25 femoral hernia the prosthesis is of truncated
26 conical shape.

27
28 In an alternative embodiment the prosthesis provided
29 for repairing or resisting the formation of femoral
30 hernia is of triangular prism shape. In another
31 embodiment, in cross section, the prosthesis is
32 substantially arrowhead shaped having two outer

1 accurate sides which extend from a base towards each
2 other to form a point. Preferably the point is
3 rounded. Alternatively, the prosthesis is
4 substantially D shaped with the accurate sides
5 forming a more rounded arched point.

6
7 In a particular embodiment the prosthesis is formed
8 from a number of component prosthetic parts which
9 together form the complete prosthesis of the first
10 aspect of the invention.

11
12 In an embodiment of the prosthesis formed from at
13 least two component parts, the parts may include
14 means to attach the parts to each other to form the
15 complete prosthesis.

16
17 It can be envisaged that the component prosthetic
18 parts are of suitable shape such that in combination
19 they provide a prosthesis which provides a channel
20 able to receive an anatomical structure.

21
22 Typically the prosthesis is formed from resilient
23 material such that the prosthesis can be flexed to
24 open the access to the channel.

25
26 Suitably the prosthesis may be constructed of
27 synthetic polymer which may be absorbable or non-
28 absorbable, mesh material formed from synthetic
29 polymer, solid material, foam or hydrogel. Suitable
30 synthetic polymers include, but are not limited to,
31 polyester, polypropylene, PTFE, Mersilene, MPathy-
32 Mesh TM and Mini-MeshTM (available from MPathy

1 Medical Devices Limited, UK).

2

3 The prosthesis may be formed from rolls of mesh
4 and/or comprises cross members to provide the
5 prosthesis with strength to resist compression. The
6 prosthesis may be formed from plastics material. In
7 a particular embodiment the foam used to construct
8 the prosthesis is polyurethane.

9

10 This is advantageous in that the channel may be
11 formed such that, in use, the prosthesis may be
12 flexed from its rest position to an open position to
13 increase the width of the access to the channel
14 enabling an anatomical structure to be more easily
15 received by the channel. The prosthesis may then be
16 released to return to its rest position wherein the
17 anatomical structure is substantially enclosed by
18 the channel when the prosthesis is located in the
19 defect.

20

21 An anatomical structure may be partially received
22 and enclosed by the channel of the prosthesis.
23 Typically an anatomical structure may be partially
24 received and enclosed by the channel such that at
25 least 30% of the circumference of the anatomical
26 structure is surrounded by the prosthesis.

27

28 The channel of the prosthesis is sized such that in
29 use an anatomical structure may pass, when the
30 prosthesis is in place in the body, without
31 substantial compression of said anatomical structure
32 by the prosthesis. Substantial compression of the

1 anatomical structure is compression which causes
2 pain to the patient or ischaemia of a distal organ.
3 Preferably the width of the anatomical structure,
4 which in use passes through the channel, is
5 compressed less than 70%, even more preferably less
6 than 50%, yet more preferably less than 40%, even
7 more preferably less than 30%, even more preferably
8 less than 20%, yet more preferably less than 10%,
9 even more preferably less than 5%, even more
10 preferably less than 3%, most preferably less than
11 1% by the channel of the prosthesis.

12
13 The level of compression experienced by the
14 anatomical structure by the prosthesis when the
15 anatomical structure passes through the channel of
16 the prosthesis is preferably not more than venous
17 pressure. Venous pressure is typically in the range
18 2 to 10 mm Hg.

19
20 In one embodiment of the prosthesis a single
21 channel, sized to receive at least one anatomical
22 structure, is provided. In another embodiment two
23 channels each sized to receive at least one
24 anatomical structure, are provided. Each channel may
25 be differently sized to receive at least one
26 anatomical structure in order to maximise the
27 support provided by the prosthesis while allowing
28 the structure(s) to pass through the one or more
29 defined channels in the prosthesis.

30
31 A plurality of channels, each channel sized to
32 receive one or more anatomical structures, may be

1 received by the prosthesis.

2

3 In a preferred embodiment of the present invention
4 the prosthesis further comprises at least one flange
5 provided on either one or both ends of the
6 prosthesis. The provision of a flange on the
7 prosthesis is advantageous as it aids location of
8 the prosthesis in the body and may provide
9 additional support to tissue, muscle or an organ
10 wall surrounding the defect. In particular
11 embodiments, the flange extends from the prosthesis
12 such that, in use, the flange provides an
13 inferomedial extension to the prosthesis. For
14 example, if a prosthesis of the invention further
15 comprising a flange is used to plug an inguinal
16 canal, a first end of the prosthesis is positioned
17 at the internal inguinal ring of the inguinal canal
18 and a second end of the prosthesis is positioned at
19 the external ring of the inguinal canal and a flange
20 present on the second end of the prosthesis, can
21 inferomedially extend from the prosthesis around the
22 external ring.

23

24 The flange may be provided by a layer of synthetic
25 mesh. Alternatively, the flange may be formed from
26 a plurality of layers of synthetic mesh.

27

28 The layer(s) of mesh may overlap each other.
29 Moreover, the layer(s) of mesh may be of any desired
30 shape to support the surrounding tissue, muscle or
31 organ wall.

32

1 It is advantageous for the flange to be constructed
2 of mesh. The mesh has minimal mass density in
3 relation to its volume. In a preferred embodiment
4 the flange is constructed of Mini-Mesh™.

5
6 A flange portion may contain structures or regions
7 capable of receiving sutures or other fixing means
8 to secure the flange around the anatomical
9 structures received by the channel and/or to secure
10 the flange to the surrounding tissue. The flange
11 may comprise more than one portion of material. For
12 example, a flange may comprise two or more portions
13 which can be arranged around an anatomical
14 structure. The two portions may attach to each
15 other or overlap each other to form an extended
16 region of support to a hernia. The portions of the
17 flange which overlap each other may be formed of
18 thinner material such that the overlapped region has
19 the same thickness as the non-overlapped region of
20 the flange.

21
22 In a particular embodiment of the prosthesis, the
23 prosthesis has a crenated outer surface. The
24 crenated outer surface allows the prosthesis to grip
25 the tissues surrounding the prosthesis and aids
26 retention of the prosthesis, in position, in the
27 body.

28
29 In a second aspect of the present invention there is
30 provided a kit of parts including a prosthesis
31 according to the first aspect of the invention and
32 synthetic mesh for overlaying the prosthesis when

1 the prosthesis is positioned in the body. The kit
2 may also include instructions as to the way in which
3 the components of the kit are to be used.

4

5 According to a third aspect of the invention there
6 is provided a method for treating a hernia
7 comprising the steps:

- 8 - exposing the hernia defect
- 9 - providing a prosthesis wholly in the extra
10 peritoneal compartment of the abdominal wall
11 to fill the defect but providing a
12 relatively pressure free passage of an
13 anatomical structure past the prosthesis.

14

15 The method is for treatment of abdominal hernia.
16 Typically the method may be used for treatment of
17 inguinal or femoral hernia.

18

19 The method may further include the step of fixing
20 the prosthesis to the margins of the defect. One
21 example of the way in which the prosthesis may be
22 fixed to the margins of the defect is by suturing.

23

24 The method may further include the step of
25 overlaying the prosthesis with mesh.

26

27 The method preferably uses the prosthesis of the
28 first aspect of the invention or the kit of the
29 second aspect of the invention.

30

1 Preferred features of each aspect of the invention
2 are as for each of the other aspects mutatis
3 mutandis unless the context demands otherwise.
4

5

6 **Brief Description of the Drawings**

7

8 Embodiments of the present invention will now be
9 discussed, by way of example only, with reference to
10 the accompanying figures in which;
11

12 Figure 1 shows a perspective view of an
13 embodiment of a prosthesis of the invention
14 from a second end;
15

16 Figure 2 shows a perspective view of an
17 embodiment of a prosthesis of the invention
18 from a first end;
19

20 Figure 3 shows a perspective view of an
21 embodiment of a prosthesis of the invention in
22 use;
23

24 Figure 4 shows an embodiment of a prosthesis
25 which further includes a flange provided at one
26 end of the prosthesis;
27

28 Figure 5 shows an indirect inguinal hernia;
29

30 Figure 6 shows a hernia repaired using a
31 conventional prosthesis of the prior art;
32

1 Figure 7 shows an illustration of the anatomy
2 around the inguinal canal; and

3
4 Figure 8 shows an illustration of the anatomy
5 around the femoral canal.

6

7 **DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS**

8

9 The invention is directed to an implantable
10 prosthesis for repairing or resisting the formation
11 of bodily hernia, in particular to plug or stop any
12 aperture in the body in which a structure is
13 required to pass through or adjacent to the
14 aperture. For example, the prosthesis may be used
15 to plug the inguinal canal or the femoral canal. In
16 these embodiments, provided by way of example only,
17 the prosthesis has a channel through which an
18 anatomical structure, such as a spermatic cord or
19 femoral vein, may pass without substantial
20 compression of the anatomic structure.

21

22 As shown in figures 1 and 2, in one embodiment, the
23 prosthesis 10 is a truncated cone having a first end
24 14 and a second end 16, wherein the diameter of the
25 first end is less than the diameter of the second
26 end 16, and an outer conic surface 15 extends
27 between the ends. An inner surface 12 forming a
28 channel is defined by a substantially scalloped
29 portion removed from the outer surface of the
30 truncated conical prosthesis. It can be envisaged
31 that the scalloped portion is formed by the removal
32 of a cylindrical portion which intersects the outer

1 conical surface 15 to create a prosthesis of
2 crescential cross-section. The prosthesis resembles
3 a wedge shape being narrower at the first end and
4 widest at its second end. An anatomical structure
5 may pass through the prosthesis whilst being
6 partially surrounded by the prosthesis to minimise
7 the pressure or compression exerted on the
8 anatomical structure.

9

10 It will be understood that the cross section of the
11 channel may be formed by at least one straight edge
12 such that the inner surface has a straight portion
13 in cross section, for example a box section channel
14 or at least one curved edge, to form a semi-circular
15 channel or other shapes as should be apparent to one
16 skilled in the art.

17

18 The channel 12 in the outer conical surface 15 of
19 the prosthesis 10 is sized to receive an anatomical
20 structure(s) which passes through the defect to be
21 repaired or supported. As shown in the illustrated
22 embodiment, figure 3, the channel formed by inner
23 surface 12 receives an anatomical structure 30 such
24 that the anatomical structure is partially located
25 in the channel. The channel minimising the
26 compression of the anatomical structure against the
27 edges of the defect when, in use, the prosthesis is
28 located in the body.

29

30 In the embodiment of the prosthesis illustrated in
31 figures 1 to 3 for use in repair of an inguinal
32 hernia the prosthesis is of truncated conical shape

1 with a semi-circular channel removed from the
2 conical surface such that the prosthesis is
3 substantially a wedge shape extending from a first
4 end 14 of minimal depth to a second end of diameter
5 of around 19 mm. The channel is of around 15 mm in
6 depth at the second end, such that in cross-section
7 the second end is crescential in shape with a
8 maximum depth (x - y see figure 1) of 7 mm. The
9 length of the prosthesis between the first and
10 second ends is around 23mm.

11
12 The portion removed from the truncated conical
13 prosthesis to provide a channel can be in the range
14 of 5 mm to 20 mm in width and depth. Although in
15 the embodiment shown in figures 1 to 3, the channel
16 is substantially semi-circular in cross section, the
17 channel may be of any shape. In addition, more than
18 one channel may be present in the prosthesis, each
19 channel being able to receive a particular
20 anatomical structure.

21
22 Typically the prosthesis is in the range 1 cm to 5
23 cm in length between the ends and around 1 cm to 4
24 cm in width and depth.

25
26 As shown in figure 3, in use, an anatomical
27 structure 30 is received by the channel 12, the
28 channel indenting the conical surface of the
29 prosthesis and linking the first and second ends 14
30 and 16, such that the anatomical structure can pass
31 from one end of the prosthesis to the other without
32 substantial compression. This differs from the

1 conventional prosthesis 100, illustrated in figure
2 6, which lacks a channel. As illustrated in figure
3 6 when a conventional prosthesis is in use to plug a
4 defect, for example in abdominal wall muscle 36 and
5 fat 34 through which a hernia 32 of viscous 38
6 protrudes, an anatomical structure 30, such as a
7 spermatic cord, is located between the prosthesis
8 100 and the edge of the defect. As the prosthesis
9 100 lacks a channel and the prosthesis is pushed
10 into the defect, the anatomical structure is
11 compressed.

12

13 The prosthesis and further the flange portion may be
14 formed from a range of material including, but not
15 limited to, polyester, polypropylene, PTFE,
16 Mersilene, MPathy-Mesh™ or Mini-Mesh™ (available
17 from MPathy Medical Devices Limited, UK).

18

19 The prosthesis may be formed using suitable
20 construction techniques, for example knitting and /
21 or weaving of monofilament or multifilament yarns,
22 moulding, ultrasonic, induction, vibration, infrared
23 or laser welding.

24

25 As illustrated in figure 4, the prosthesis of the
26 present invention may further comprise a flange 18.
27 The flange may extend laterally from at least a
28 first or second end or both ends of the prosthesis.

29

30 As shown in figure 4, when the prosthesis is located
31 in the defect, the flange 18, which extends from the
32 second end of the prosthesis, can aid the

1 positioning of the prosthesis, in the inguinal
2 canal. Further, the flange may be formed from mesh
3 and extend from the prosthesis such that when the
4 prosthesis is implanted in the body the mesh extends
5 to the musculature surrounding the inguinal canal
6 and provides support thereto. In particular
7 embodiments, the flange can extend from the
8 prosthesis inferomedially, which aids the use of the
9 prosthesis in the treatment of direct inguinal
10 hernia.

11
12 The flange may include more than one layer of mesh
13 and said layers may overlap each other. Moreover,
14 the flange may include cut out portions to allow it
15 to be placed around or over protruding structures or
16 attachment means to attach the flange to itself and
17 / or tissue, muscle etc. Such attachment means
18 include sutures or other fixing means.

19
20 In embodiments wherein a flange is provided on both
21 ends of the prosthesis, the flange, when the
22 prosthesis is in use, may be provided around the
23 internal ring and external ring of the inguinal
24 canal such that the tissue and fascia around the
25 inguinal ring is sandwiched between at least two
26 layers of mesh. The flange thus supports the tissue
27 and/or fascia and minimises the likelihood of organs
28 or structures rupturing or protruding through the
29 tissue and/or fascia.

30
31 An embodiment of the prosthesis of the first aspect
32 of the invention can be utilised to repair or resist

1 the formation of an inguinal canal.

2

3 As illustrated in figures 7 and 8 the sac of an
4 indirect inguinal hernia 40 may extend from the
5 external ring 42 of the inguinal canal 44. The
6 inguinal canal extending between the external ring
7 42 and an internal ring 46.

8

9 In use, a prosthesis is inserted into the inguinal
10 canal such that a first end of the prosthesis is
11 positioned at the internal inguinal ring 46 and the
12 second end is positioned at the external ring 42 of
13 the inguinal canal. When located in the inguinal
14 canal 44 the prosthesis acts to minimise the
15 protrusion of organs or the other body parts through
16 the inguinal canal, but as the prosthesis includes a
17 channel, there is provided a passage for selected
18 anatomical structures, such as the spermatic cord,
19 to pass through the prosthesis without being
20 substantially compressed by the prosthesis or
21 between the prosthesis and the surrounding tissue.

22

23 To aid the fixation of the prosthesis in the
24 inguinal canal the prosthesis may be crenated on its
25 outer surface. Such crenations will project from the
26 outer surface of the prosthesis into the surrounding
27 tissue and minimise the movement of the prosthesis
28 once it has been suitably positioned.

29

30 An embodiment of the prosthesis of the invention may
31 be used to repair or resist the formation of a
32 femoral hernia. As illustrated in figures 7 and 8

1 the femoral canal 48 lies between the fascia
2 transversalis 50 and fascia iliaca 52 with the
3 femoral vein 54, femoral artery 56 and femoral nerve
4 58 being present to one side of the femoral canal.
5 As shown in figure 7, a sac of a femoral hernia 60
6 may extend along and pass out of the femoral canal.

7
8 In use, an embodiment of the prosthesis for
9 treatment of femoral hernia may be inserted into the
10 femoral canal to minimise the protrusion of the
11 hernia sac through the femoral canal. During
12 insertion of the prosthesis into the femoral canal,
13 the channel of the prosthesis is orientated such
14 that expansion of the femoral vein is into the
15 channel of the prosthesis. Thus, in contrast to
16 conventional prosthesis, the compression of the
17 expanded vein against the prosthesis and / or the
18 surrounding tissue will be minimised. In addition,
19 the channel will still provide for movement in the
20 lymphatic system from a lower limb to external iliac
21 nodes.

22
23 In one embodiment, a prosthesis of the present
24 invention, for use in plugging the femoral canal, is
25 substantially of triangular prism shape in cross
26 section such that it is shaped to fit into the
27 femoral canal. In another embodiment, in cross
28 section, the prosthesis is substantially arrowhead
29 shaped having two outer accurate sides which extend
30 from a base towards each other to form a point.
31 Preferably the point is rounded. Alternatively, the
32 prosthesis is substantially D shaped with the

1 accurate sides forming a more rounded arched point.
2 In each embodiment a channel is provided in the
3 outer surface of the prosthesis to receive the
4 femoral vein when it is expanded. When the
5 prosthesis is substantially arrowhead or D shaped,
6 it is preferred that the base portion is indented
7 towards the point to receive an anatomical
8 structure.

9
10 The prosthesis is sized such that it can be suitably
11 located into the femoral canal. In particular
12 embodiments the prosthesis is sized such that it is
13 of length in the range 1 cm to 5 cm, of width at a
14 first end for insertion into the femoral canal in
15 the range 0.5 cm to 3 cm and a second end at 0.5 cm
16 to 5 cm.

17
18 The channel need only be an indentation in the outer
19 surface of the prosthesis to receive the femoral
20 vein when expanded such that the pressure exerted on
21 the vein, during expansion of the vein, by the
22 prosthesis is minimised.

23
24 As discussed above, a prosthesis for use in treating
25 femoral hernia may further include a flange at
26 either or both ends of the prosthesis, wherein the
27 flange extends around the femoral canal and thus
28 supports the surrounding tissue or fascia. As
29 previously discussed such a flange may also contain
30 cutouts to accommodate structures such as the
31 femoral nerve and / or artery.

32

1 The prosthesis of the present application has been
2 designed to take into consideration the anatomical
3 structures and properties of the inguinal and
4 femoral canal to minimise the disruption of these
5 structures following location of the prosthesis.

6
7 Various modifications can be made without departing
8 from the scope of the invention, for example,
9 flanges extending from the faces of the prosthesis,
10 as discussed above, may be formed from material with
11 memory, such that following placement in the body
12 the flanges move from a collapsed position to an
13 extended position to secure the prosthesis in the
14 body.